AF1641

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Stan Cipkowski

Serial No. 08/981,665 Group Art Unit 1641

Filed: November 5, 1997 Examiner J. Grun

For: DEVICE FOR THE COLLECTION, TESTING, AND SHIPMENT OF BODY FLUID SAMPLES

The Commissioner of Patents and Trademarks

Washington, D.C. 20231

ATTENTION: Board of Patent Appeals and Interferences

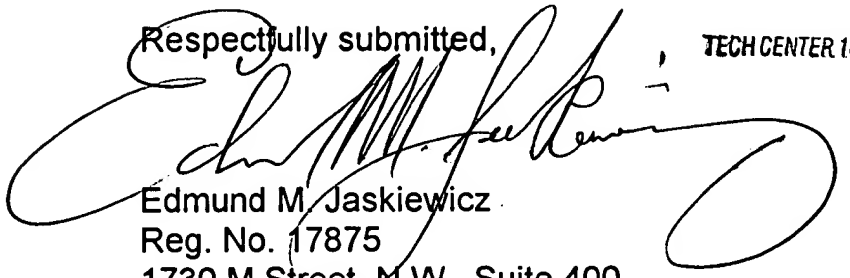
TRANSMITTAL OF APPELLANT'S AMENDED BRIEF (37 CFR. 1.192)

Transmitted herewith in triplicate is the Amended Appeal Brief in this application in response to the Notification of Non-Compliance of May 26, 2000 (Paper No. 20).

The Brief has been amended to include headings identifying the real party in interest and any related appeals and interferences. Further, the Amended Brief

sets forth the real party in interest and describes a pending appeal in a trademark application.

Respectfully submitted,



Edmund M. Jaskiewicz
Reg. No. 17875
1730 M Street, N.W., Suite 400
Washington, D.C. 20036
(202) 296-2900

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PATENT

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APPELLANT'S BRIEF (37 CFR. 1.192)
AMENDED

This amended brief is in furtherance of the Notice of Appeal filed in this case on December 10, 1999 and in response to the Notification of May 26, 2000 (Paper No. 20)..

The fees required under § 1.17(f) and any required petition for extension of time for filing this brief and fees therefor were dealt with in the previous Transmittal of Appeal Brief.

This amended brief is transmitted in triplicate.

This amended brief contains these items under the following headings and in the order set forth below (37 CFR 1.192(c):

I REAL PARTY IN INTEREST

II. RELATED APPEALS AND INTERFERENCES

III. STATUS OF CLAIMS

IV. STATUS OF AMENDMENTS

VI. SUMMARY OF INVENTION

VI. ISSUES

VII. GROUPING OF CLAIMS

VIII. ARGUMENTS

VID REJECTIONS UNDER 35 U.S.C. 103

IX. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

The final page of this amended brief bears the attorney's signature.

I. REAL PARTY IN INTEREST

The real party in interest is American Bio Medica Corporation, a corporation of the State of New York and located at 122 Smith Road, Kinderhook, New York 12106 and assignee of the subject application by an assignment executed October 28, 1997 and recorded on November 5, 1997 on Reel 9084, Frame 0350 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

The above assignee has appealed its U.S. Trademark Application Serial No. 75/188002 RAPID DRUG SCREEN to the Trademark Trial and Appeal Board and this appeal is now pending. There are no other related appeals or interferences.

III. STATUS OF CLAIMS

Claims in this application are: 16-19.

The status of all of the claims is that the claims have been rejected.

The claims on appeal are 16-19.

IV. STATUS OF AMENDMENTS

An Amendment After Final Rejection was filed March 21, 2000 with amendments to claim 16 and setting forth arguments discussed at the interview with Examiner on February 9, 2000.

An Advisory Action was issued April 27, 2000 and the claims again were rejected.

The Amendment After Final Rejection was entered by the Examiner for the appeal.

V. SUMMARY OF INVENTION

The invention is a drug of abuse test card having an end which is inserted into a fluid sample, usually urine, to detect the presence of a drug of abuse in the sample. The card carries thereon a plurality of immunoassay test strips so mounted that a first portion of the test strips contacts and receives the fluid sample and a second portion of the test strips visually indicates presence or absence of a selected drug of abuse. In these test strips, the fluid sample moves by capillary action through the material of each test strip from the first portion of the strip to the second or test portion of the strip in what may be described as a continuous flow. Such test strips are generally referred to in the industry as "lateral flow" strips.

The test card is usually inserted longitudinally through an opening, generally a slit in the top of a container having a fluid sample therein, until the first portion of the test strips contacts the fluid sample.

The test card comprises one or more immunoassay test strips disposed between the front and rear surfaces of a thin flat member such that the ends of the test strips terminate short of the ends of the test card and are enclosed therein. Access to each test strip is only through a pair of openings in the front surface of the test card spaced longitudinally to register with and expose the sample and test portions of each of the test strips. Each test strip is thus fully protected during insertion and withdrawal of the test card through the opening in the top of a container and human contact with the test strips on the test card is prevented without the necessity for sealing or enclosing the individual test strips.

The construction of this test card is such so as to avoid any contact between the person being tested, the person carrying out the test, and the fluid sample to be tested. There is no necessity for any dispensing or application of the fluid sample to be tested onto a test strip. At the same time, the test strip ensures proper contact of the test strip with the fluid sample and facilitates reading of the visual results.

VI. ISSUES

Whether claims 16-19 are unpatentable under 35 USC 103 over Sun, et al. in view of Boger, either with Davis or Lee-Owen and any of Huang or Norell.

VII. GROUPING OF CLAIMS

Claim 16 is independent and claims 17-19 are dependent therefrom. The rejected claims stand or fall together.

VIII. ARGUMENTS - REJECTIONS UNDER 35 USC 103

Since the rejection of the claims is based upon a combination of the Sun and Boger references, the disclosures and teachings of each of these references must be considered.

Sun discloses a lateral flow immunoassay test strip which is completely enclosed between two pieces of plastic that are welded together to fabricate a plastic housing of a test device. No portions of the test strip in Sun are directly exposed to the atmosphere through spaced openings in a front surface of the test device. Fig. 1a of Sun shows that a surface of the plastic housing is provided with an opening 107 which is a reception cavity for the fluid sample to be tested and the fluid sample must then flow through a passage 108 before coming into contact with test strip 102. The Sun

test device is not intended to be dipped into a fluid sample but he specifically discloses that drops of the fluid sample are added to the sample opening 107 such as with a dropper. No portion of test strip 102 is exposed to the atmosphere to provide a visual indication of the test results until an outside sleeve 105 is moved longitudinally to reveal a view window area (which is not illustrated in the drawings). Thus Sun discloses a housing for an immunoassay test strip wherein the fluid sample will flow by capillary action, or lateral flow, from one portion of the test strip to another, while the test device is maintained in substantially a horizontal position.

Boger discloses a holder for positioning and retaining a number of individual reagent test pads or devices of the type which reveal a color change in the presence of a specific test sample component or constituent. The holder is provided with a number of openings to expose each reagent test pad for the application of a fluid sample. The ends of the test devices project outwardly of the holder as shown in Fig. 2 of the Boger drawings and function as handle portions. Preferably, the sample to be tested is applied to each of the individual test pads but Boger also suggests that the entire holder can be dipped into the sample to be tested. Boger discloses that these test devices might be of an immunochemical structure which means that these devices could be made for an antigen-antibody reaction but does not suggest in any way that such test pads are lateral flow. The nature of these test pads is clearly described in column 1, lines 44-64 of Boger.

Boger is not concerned with the reading of the test results while the test strips are in the holder, and, indeed, discloses no such structure for doing this. In Boger, the

strips are removed from the holder and then are checked for results. There is no teaching in Boger of providing both sample receiving and test openings for each test strip and for enclosing the test strips within the outline of the holder. All of the openings 18 disclosed in Boger are intended only for the applications of samples. While Boger does suggest that the entire holder can be dipped into the sample to be tested, there is no suggestion or teaching of the reading of the results of tests on the test pads until after the holder has been opened and the test pads have been removed therefrom.

Thus, the test devices in the Sun and Boger patents are wholly dissimilar from each other and represent significantly different approaches to testing. The Boger test device is a reagent pad impregnated with chemicals which react to a particular drug to produce a change in color. Sun uses an immunoassay test strip wherein the fluid sample is applied to an end portion of the test strip /having latex spheres coated with detecting antibodies, the sample and the spheres traverse the membrane to a drug conjugated probe which serves as a test that the device is operative and continues to migrate to a third portion where the spheres complex with protein antigen immobilized at a second probe or testing area. The concepts and approaches of the Boger and Sun test devices are wholly dissimilar as is evident.

In Sun, no portion of the immunoassay test strip is exposed to the atmosphere; the fluid sample being applied through an opening and then flows through a passage to the test strip itself within the Sun plastic holder. Boger merely shows openings to expose the test pad and to enable a fluid sample to be applied to the test pad. Boger

does not teach any second openings in his holder for observing test results, and, indeed, needs no second openings since the test results are visible in the first opening. Boger states that in his Fig. 3, a holder for single pad reagent devices is shown in which the top member of the holder contains a single opening 22-22 for each reagent test device. There are what appear to be on the top member of the Boger device rectangular recesses or other rectangular structures but there is not the slightest indication in the specification as to what these rectangular structures are and hence, there is no teaching of second openings on the top surface of Boger. It is thus unlikely that one skilled in the art having the Sun test device before him would investigate the Boger test device which uses pads and has no second openings to determine the desirability of placing a second opening in the Sun housing to observe test results.

Appellant's claim 16 was amended to recite that the fluid sample flows by capillary action to the test portion of the strip so as to limit appellant's claim to an immunoassay test strip which is wholly different from the reagent test pads disclosed in Boger.

It is thus submitted that because the reagent test pad in Boger is completely different from the lateral flow immunoassay test strip of Sun that it is most unlikely one versed in the art would look to the Boger holder of test pads in which to mount lateral flow test strips. There does not appear to be any basis for combining Boger with Sun, as alleged by Examiner, as an anticipation of appellant's invention as recited in claim 16. Since the Boger and Sun holders are for vastly different test devices there is no interchangability of these holders without significant modification. The same arguments

would also apply if it were attempted to combine the Sun patent with Boger used as the basic reference.

With respect to the further references cited by the Examiner in his final rejection of the claims, Davis discloses an analytical specimen cup having a lid with spaced partitions therein to define a test space between the partition and the test strip is mounted in this test space. The fluid sample to be tested is caused to flow into the chamber in the lid in which the test strip is mounted. There is no teaching of submersion of the test device into a sample.

Lee-Owen shows a test strip which is totally enclosed and sealed with a fill or tape to provide a packaging pouch for the test strip. However, in order to use the Lee-Owen test strip, additional procedures are necessary which include cutting off a portion of the package to expose an end of the test strip as shown at 16 in Fig. 1. Thus, the end of the test strip is not protected but forms an end of the package and both ends of the test strip are not spaced from the ends of the card. Lee-Owen does not disclose or suggest an opening in the surface of his package spaced from the bottom of the package for receiving the fluid sample.

Huang merely discloses a lateral flow test strip of a type similar to that utilized in appellant's test card. He specifically states that this is a test strip without a plastic housing. Merely having this test strip in front of one skilled in the art would in no way suggest the mounting of this test strip in a test card as proposed by appellant since this patent is concerned only with the construction of this test strip *per se.*

Norell shows a testing device 20 having testing elements for the analysis of a

sample. The sample being tested is placed in a well 30 in the back panel so as to contact the sample application pad 62 on test strip 60. The sample receiving portion is not open and exposed through the front panel but is covered by the absorbent pad 72.

Appellant has thus invented a greatly simplified test card which is particularly adapted for insertion through an opening in the top of a container to contact a fluid sample within the container or to place the test card in direct contact with a reservoir of fluid sample. The immunoassay test strips are enclosed within the test card so as to be completely protected, but the only portions of the test strips visible to the atmosphere are the sample receiving and test portions which are visible through spaced openings in the front face of the test card. No combination of the cited references teaches or even suggests that this structure as invented by appellant and as recited in claim 16.

IX. APPENDIX OF CLAIMS

The text of the claims on appeal are:

16. A drug of abuse immunoassay test card for testing of fluid samples in a container having an open top and comprising a thin flat member having a rectangular outline and having front and rear surfaces, said thin flat member having a longitudinal dimension extending between top and bottom ends defining a length and having a width less than said length, and being shaped to be insertable longitudinally into a container to contact a fluid sample therein, one or more immunoassay test strips each having thereon immunoassay means to visually indicate presence or absence of a selected drug of abuse disposed longitudinally side-by-side in parallel within said thin flat member and enclosed between said front and rear surfaces, each said one or more

test strips having a bottom end defining a sample receiving portion and further having a test portion spaced longitudinally therefrom wherein, in use, the fluid sample moves by capillary action to the test portion at which the presence or absence of the selected drug of abuse in the fluid sample is visually indicated, the bottom end of each said one or more test strips being disposed at the bottom end of said thin flat member but spaced from the bottom end of said thin flat member, the top end of each said one or more test strips being spaced from the top end of said thin flat member, said front surface of said thin flat member having a plurality of openings therein to register with and expose each of the sample receiving and test portions of each of said one or more test strips.

17. The drug of abuse immunoassay test card as claimed in claim 16 further comprising means within said thin flat member between said front and rear surfaces for defining one or more longitudinally extending slots to longitudinally dispose said one or more test strips, each said one or more slots having both ends closed and spaced from the respective top and bottom ends of said thin flat member, and said one or more immunoassay test strips each seated within a respective slot.

18. The drug of abuse immunoassay test card as claimed in claim 16 wherein said thin flat member comprises a central ply having a first thickness sandwiched between a top ply defining said front surface and a bottom ply defining said rear surface, there being a plurality of side-by-side parallel longitudinally extending slots in said central ply to longitudinally dispose said test strips, said slots having both ends thereof closed and spaced from the respective top and bottom ends of said thin flat

member, and said immunoassay test strips each seated within a respective slot.

19. The drug of abuse immunoassay test card as claimed in claim 16 wherein said thin flat member has a thickness substantially equal to the thickness of said test strips.

Respectfully submitted,

Edmund M. Jaskiewicz
Reg. No. 17875
1730 M Street, N.W., Suite 400
Washington, D.C. 20036
(202) 296-2900